



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/752,095	01/07/2004	Bill E. Cham	P07389US01/BAS	2329
881 7590 06/08/2009 STITES & HARBISON PLLC 1199 NORTH FAIRFAX STREET SUITE 900 ALEXANDRIA, VA 22314				
EXAMINER PESELEV, ELLI				
ART UNIT PAPER NUMBER 1623				
MAIL DATE DELIVERY MODE 06/08/2009 PAPER				

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/752,095

**Applicant(s)**

CHAM, BILL E.

**Examiner**

Elli Peselev

**Art Unit**

1623

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 05 March 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 24-32, 43-53 and 64 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 24-32, 43-53 and 64 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB-08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 24-32, 43-53 and 64 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cham et al (Cancer Letters, 55 (1990) 221-225).

Cham et al disclose a composition comprising glycoalkaloids (BEC) useful for treating cancer (page 221). Cham et al further disclose that rhamnose inhibits the efficacy of BEC and that the aglycone solasodine is not effective against murine S180 (page 221). Thus, a person having ordinary skill in the art at the time of the present invention would have been motivated to remove rhamnose and aglycones from the BEC composition in order to improve efficacy of BEC.

Claims 30, 31, 51 and 52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cham et al (Cancer Letters, 55 (1990) 221-225) in view of Daniels et al (U.S. Patent No. 4,053,591).

Cham et al disclose that aglycone solasodine is not effective against murine S189. Thus a person having ordinary skill in the art at the time the claimed invention was made would have been motivated to remove aglycones from the composition disclosed by Cham et al using conventional chloroform purification process disclosed by Daniels et al (column 14, lines 50-52).

Applicant's arguments filed March 5, 2009 have been fully considered but they are not persuasive.

Applicant contends that one of ordinary skill in the art would not have been motivated to remove rhamnose and aglycones from BEC composition because Cham does not teach that rhamnose and aglycones are present in the BEC composition as degradation products. This argument has not been found persuasive since Cham et al disclose that rhamnose inhibits efficacy of BEC and that aglycones are not effective against tumors. Thus, a person having ordinary skill in the art at the time the claimed invention was made would have been motivated to remove rhamnose and aglycones, whether the rhamnose and aglycons resulted from addition, degradation or any other source. Also, Cham et al discloses that solasodine is not effective against murine S189. Thus, a person having ordinary skill in the art at the time the claimed invention was made would have been motivated to remove solasodine, which was known to have no efficacy. It is generally acknowledged that it is desirable for the active component in the pharmaceutical composition to be as pure as possible. Thus, the removal of degradation product in a pharmaceutical composition, in order to further purify a pharmaceutical composition, would have been prima facie obvious to a person having ordinary skill in the art at the time the claimed invention was made. Applicant also contends that if the component has a minor effect on the efficacy of a composition, yet if its removal would significantly complicate the manufacturing process, then it is not desirable to remove the component. This argument has not been found persuasive since Cham discloses that rhamnose inhibits efficacy of BEC. From the teaching by

Cham, a person having ordinary skill in the art at the time the claimed invention was made would have expected that any rhamnose, whether resulting from addition or degradation, would inhibit the efficacy of BEC. Further, the present claims are not limited to a manufacturing process but read on conventional purification methods. Also, applicant has not presented any evidence in verified form that the purification of glycoalkaloid composition would significantly complicate the manufacturing process.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elli Peselev whose telephone number is (571) 272-0659. The examiner can normally be reached on 8.00-4.30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Jiang can be reached on (571) 272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Elli Peselev  
/Elli Peselev/  
Primary Examiner, Art Unit 1623